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January 22, 2013

VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Federal Bldg. & U.S. Courthouse
402 East State Street
Room 6052
Trenton, NJ 08608

Re: AstraZeneca, et al. v. Hanmi, et al., Civil Action No.: 11-0760(JAP)(TJB)

Dear Judge Bongiovanni:

We, along with Sughrue Mion, PLLC, represent the Hanmi Defendants (“collectively Hanmi”) in the above-captioned action. Hanmi respectfully submits this letter in response to AstraZeneca’s January 15, 2012 letter to Your Honor (“Submission”) seeking an Order compelling Hanmi to respond to AstraZeneca’s belatedly served Requests for Admission.

First, for the same reasons as we advised in our January 15th letter to the Court, AstraZeneca’s submission should be dismissed for not complying with the Court’s Letter Order of May 12, 2011, D.I. 56, page 3, last paragraph (counsel shall not raise a discovery dispute by letter without first filing a formal motion, despite aspects of the Local Rules to the contrary).

Second, AstraZeneca urges that the discovery sought relates to “identify[ing] the patent claim term(s) whose construction forms the basis for Hanmi’s non-infringement assertion” (Submission, p. 1), allegedly raised in Hanmi’s Motion to Amend concerning “hydrates,” filed October 15, 2012 (D.I. 238). However, AstraZeneca’s Opposition to the Motion to Amend (D.I. 244) ***never requested that fact discovery was needed in order to respond to Hanmi’s motion.*** Thus, at the time of the November 28, 2012 call with Your Honor, no requests to take fact discovery out of time had been raised. AstraZeneca’s request for additional *Markman* briefing in connection with Hanmi’s Motion to Amend is a completely separate issue from belated service of over 100 Requests for Admission after the close of discovery -- the vast majority of which have nothing to do with any issue raised in Hanmi’s Motion to Amend.



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If the submission is considered, the relief requested should nonetheless be denied.

1. AstraZeneca's RFAs Were Late

It is undisputed that the fact discovery cut off in this case was November 20, 2012, and that AstraZeneca's RFAs were served on November 30, 2012, ten days after the close of fact discovery. The deadline for serving written discovery was October 19, 2012. *See* Ex. 5 to AstraZeneca's January 15th Submission (Hanmi's January 2, 2013 letter and Objections). It is undisputed that AstraZeneca never sought the approval of the Court to belatedly serve its RFAs under Fed. R. Civ. P. 29(b). AstraZeneca argues that its RFAs were nonetheless *timely* served because Your Honor "instructed" them to propound discovery during the phone conference of November 28, 2012 (Submission, p. 3, 4) -- *notwithstanding any preexisting discovery schedule* - - "consistent with a Court's plenary power to manage discovery." *Id.* at 4.

Hanmi disagrees that, as a result of the November 28, 2012 phone conference, fact discovery was reopened, or that the Court "instructed" AstraZeneca to serve new discovery. Rather, Hanmi understood Your Honor to suggest that the parties try to *agree* upon a schedule going forward for both expert discovery and any discovery the parties *agreed* could be taken in respect of AstraZeneca's claim construction issue:

- But I'm wondering if what I can have you folks do is agree upon a schedule that gives you a period of time following a decision to wrap things up. (Tr. 6)
- But I'm happy to defer to you folks. If you want to have a schedule in mind in principle, or even on the -- on the record, an order entered, but with the right to tell me and ask me for an emergent call once you get your ruling, to talk about what that does; whether it's your ruling on claim construction or whether it's a ruling on the amendment to the contentions. I'm happy to do that. (Tr. 10)
- So what I'm hearing is that you view the amendment to require additional discovery because new issues were raised; Hanmi says, not so. Your position, Astra's position is, though, that if you have additional time to do this discovery, then you wouldn't have an objection to the amendment. And if that's right, can you accomplish and proceed with the discovery on the amendments, regardless of how the claim construction ruling comes out? Since it's not going to come out tomorrow, can you work on that during the month of December, and then alleviate your -- (Tr.17)
- THE COURT: Okay. Well, that's what I would like you to do, meet and confer about a proposed schedule. (Tr. 18)
- The other thing is, certainly, if you can, meet and confer about addressing giving Hanmi -- the instruction that Hanmi should address AstraZeneca's concerns, and perhaps agree to engage in the additional discovery that would eliminate their objection, even though Hanmi obviously is saying, we don't think that it changes



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things. But if you can come up with an agreement and get that done, so that we're not wasting more time because, obviously, if there is a ruling that says they can amend and there is a request by Astra to conduct more discovery, then that's more delay, not only for you folks writing, but for me or Judge Pisano deciding, and then you folks getting the work done.

So if you can come up with an agreement that would eliminate that issue, especially because we're not having expert discovery conducted now and it could potentially be a couple of more weeks, if not longer, that would be terrific. (Tr. 18-19).

See Ex. 3 to January 15th Submission. Hanmi thus understood that the parties were to meet and confer to see if agreement could be reached about a proposed schedule going forward, which Hanmi initiated and which has led to separate correspondence with the Court. Hanmi did not understand the Court to authorize the service of new discovery on any issue in the case several days later, nor did any subsequent docket entry reflect a change to, or extension of, the November 20 fact discovery cutoff date set forth in (D.I. 230).

Although the parties attempted to work out a schedule subsequent to the November 28 phone conference, they were unsuccessful. And, AstraZeneca never sought Hanmi's agreement to extend the existing schedule (D.I. 230) to permit AstraZeneca's belated service of new RFAs on November 30. To be clear, the RFAs largely have nothing to do with Hanmi's Motion to Amend which relates to hydrates; instead, they relate to other aspects of Hanmi's product, Hanmi's NDA, Hanmi's patent, administration, effects, etc. All of these RFAs could have been served well before the discovery cut off, but AstraZeneca elected not to do so. Because AstraZeneca's RFAs were served out of time, and without authorization, Hanmi was not obligated to respond to them and AstraZeneca's present request should be denied.

2. RFA Are Discovery Tools, Subject To Fact Discovery Cut off Dates

RFAs are a form of written discovery and should be subject to the same November 20 fact discovery cutoff date as all other discovery. Rule 36 is included in the chapter of the Federal Rules governing disclosures and discovery, and Fed. R. Civ. P. 26(e)(1) treats requests for admissions no differently than other written discovery - interrogatories and requests for production. A plain reading of the Rules demonstrates that requests for admissions are subject to the rules applicable to other discovery tools, including Rule 16(b)(3) under which discovery deadlines are fixed in scheduling orders. *Gluck v. Ansett Austl. Ltd.*, 204 F.R.D. 217 (D.D.C. 2001).

In this district, the Court in *DirectTV, Inc. v. Seijas*, 2005 U.S. Dist. LEXIS 10675 (D.N.J. Feb. 9, 2005) (Chesler, J.) stated that "Requests for Admission are indeed a discovery vehicle and are utilized by parties as a way to narrow issues for trial." *Id.* at *9, n. 3, citing *United Coal Cos. v. Powell Constr. Co.*, 839 F.2d 958, 967 (3d Cir. 1988). Other courts have similarly reasoned that requests under Rule 36 are considered discovery and subject to discovery limitations. *Revlon Consumer Prods. Corp. v. Estee Lauder Cos.*, 2001 U.S. Dist. LEXIS 6616 at *2-3 (S.D.N.Y. May 16, 2001) ("[t]here should be no doubt that Requests for Admissions



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pursuant to *Fed. R. Civ. P. 36* are a discovery device”); *Coram Health Care Corp. of Ill. v. MCI Worldcom Comm. Inc.*, 2001 U.S. Dist. LEXIS 18909 (N.D. Ill. Nov. 15, 2001) (“A request for admissions is a form of discovery. [Rule 36] provides defendants thirty days to respond to a request for admissions. Defendants did not have an opportunity to timely submit their responses within the discovery period. Because Coram’s conduct violated this court’s standing order, defendants were under no obligation to respond to the request for admissions.”) *Id.* at *9. As a discovery tool, AstraZeneca’s RFAs were untimely when served on November 30.

AstraZeneca argues that some courts have permitted RFAs to be served after the close of fact discovery, and that some courts have treated RFAs as “distinct from traditional discovery tools given their purposes.” (Submission, p. 4, *citing, e.g., Synthes v. Globus Medical, Inc.*, 2006 WL 3486544, at *1 (E.D. Pa. Nov. 29, 2006) (attached as Exhibit A) and *Langer v. Monarch Life Ins. Co.*, 966 F.2d 786, 803 (3d Cir. 2006)). Neither case helps AstraZeneca. In *Synthes*, in an unpublished memorandum opinion, defendants were ordered to respond to RFAs over their objections that “the sheer number of requests, their repetitiveness, and remote relevance is grossly oppressive and abusive.” (Ex. A, p. 1). There was no allegation that the RFAs were served out of time. In *Langer*, the Third Circuit stated in *dicta* that admissions under Rule 36 are binding, and serve to narrow issues for trial. *Id.* at 803. Neither of these cases serve as authority for Hanmi to respond to AstraZeneca’s belatedly filed requests.¹

AstraZeneca relies upon *O’Neill v. Medad*, 166 F.R.D. 19 (E.D. Mich. 1996) in urging that requests for admission are distinct from traditional discovery tools given their purposes (and presumably are not subject to fact discovery cutoff dates). (Submission at 4). *O’Neill* doesn’t apply here. In *O’Neill*, the Court was bound by Sixth Circuit law dictating that requests for admissions *were not* considered discovery devices that were subject to discovery cut off dates. *Id.* at 21, *citing Misco, Inc. v. United States Steel Corp.*, 784 F.2d 198 (6th Cir. 1986). The Court reasoned:

Rule 36 is not a discovery device at all because it assumes that the party proceeding under it already knows the fact or has the document and merely seeks the opposing party to authenticate its genuineness. *Id.*

The two purposes of a request for admissions are to allow elimination of contested issues from a case prior to trial and to avoid including extraneous evidence regarding issues not in dispute and which can be developed by the process provided for in Rule 36. [citation omitted].

¹ As Judge Salas observed in *RLA Marketing, v. Wham-O*, 2007 U.S. Dist. Lexis 16629 (D.N.J. March 5, 2007), “[u]nfortunately, neither *Synthes* nor *Langer* provide this Court with a Rule. The language in *Synthes* and *Langer*, as cited by RLA is pure dicta. *Synthes* and *Langer* simply restate the status quo in this District regarding Requests for Admissions.” *Id.* at *11.



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In fact, requests for admissions are similar in nature to a pretrial order, which narrows issues and eliminates those issues with which there is no dispute.

There is no analogous Third Circuit authority that mandates a similar result in this case. To the contrary, RFAs *are* discovery tools in this district, *DirectTV, Inc.* at *9, n. 3 *supra*, and AstraZeneca has confirmed throughout its Submission that its RFAs *are* discovery tools, subject to the rules governing fact discovery in this case. In its Submission, AstraZeneca states

- “this Court . . . ***authorized the parties to take discovery*** in an effort to resolve the new claim construction issue” (p. 4)
- “AstraZeneca’s RFAs Are an Appropriate Mechanism ***to Obtain Relevant Discovery***” (p. 5)
- “***A party is entitled to discovery*** of information “relevant to any party’s claim or defense.” (p. 5)
- “***These reflect AstraZeneca’s attempt to obtain discovery*** on the hydrates issue. . .” (p. 6)
- “***This effort to obtain relevant discovery*** and narrow issues in dispute is well within the purposes of Rule 36.” (p. 6)

Having conceded its RFAs were discovery tools, the cases on which it relies are inapplicable, and its RFAs are subject to the fact discovery cutoff date of November 20. *Coram Health Care* at *9; *DirectTV, Inc.* at *9, n. 3.

3. AstraZeneca’s RFAs Have Nothing To Do With Its Illusory Claim Construction Issue

Since Hanmi filed its Motion to Amend on October 15, 2012, AstraZeneca has incorrectly tried to persuade Hanmi and the Court that yet another new claim construction issue exists in this case.

The term “hydrates” is not present in any patent claim. AstraZeneca has pressed Hanmi to identify which claim terms are to be construed to *exclude* “hydrates,” the term that isn’t there anyway. On multiple occasions, Hanmi has told AstraZeneca that there is no claim term to construe, and therefore no claim construction issue.² That’s it. That’s the dispute.

Indeed, AstraZeneca’s request that Hanmi identify, and the Court construe, a claim term that *doesn’t* recite “hydrates” in order to determine that it is *not excluded* is merely another attempt to prolong this litigation. In furtherance of its charade, AstraZeneca told the Court it

² These communications are reflected in the record following the November 28 conference call.



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needed discovery on the “claim construction issue” and propounded 124 RFAs supposedly directed to that issue.

But AstraZeneca misled the Court when it represented in its January 15 Submission that “these RFAs were tailored to identify the patent claim term(s) whose construction forms the basis for Hanmi’s noninfringement assertion.” (Submission, p. 1). They clearly do not. In fact, not a single request is directed to claim construction.³ All are directed at basic discovery -- having nothing to do with claim construction on “hydrates”-- that could and should have been served a long time ago. The very examples AstraZeneca provides in its submission are representative.

Request number 2 seeks an admission that: **Hanmi’s Drug Products contain esomeprazole strontium tetrahydrate.** (Submission, p. 5). This is a matter contained in Hanmi’s NDA, a document served almost 2 years ago, and is directed toward the issue of infringement, not claim construction. Request No. 2 has nothing to do with claim construction, because neither Hanmi’s product nor anything in Hanmi’s NDA bears on the construction of the claim terms, as AstraZeneca has represented to the Court.

Similarly, Request Nos. 7, 20, 23, 45, and 63 (Submission p. 5-6) also seek admissions about Hanmi’s products for purposes of infringement, not about claim construction. Nothing about the composition of Hanmi’s product bears on the construction of any claim term of the ‘504 or ‘192 patents. Transparently, by seeking admissions that Hanmi’s **esomeprazole strontium tetrahydrate** product is a solid (Request No. 7), pure (Request No. 20), a salt of esomeprazole (Request No. 23), prepared under alkaline conditions (Request No. 45), and has an optical purity of at least 94% (Request No. 63), AstraZeneca has already assumed “hydrates” are encompassed within the claims and seeks admission to aid in proving its infringement case. No reason exists why these Requests could not have been served during fact discovery.

In short, AstraZeneca’s RFAs have nothing to do with its present claim construction issue based on Hanmi’s Motion to Amend. They are directed to basic discovery issues and should have been served a long time ago. AstraZeneca deliberately waited until after the close of fact discovery to serve them, clearly intending to burden Hanmi and the Court with still another argument to delay the trial of this case.

Conclusion

AstraZeneca’s RFAs were served late, its excuses seeking to tie them to Hanmi’s Motion to Amend and the Court’s directives are transparent and incorrect, and Hanmi was not obligated

³ All 124 Requests are directed to Hanmi’s NDA, Hanmi’s proposed drug products, Hanmi’s patents, Hanmi’s proposed label, etc. – none of which is relevant to claim construction. Some of the requests seek admissions as to future events (Nos. 113-124), and some cannot possibly have any relationship to Hanmi’s Motion to Amend on hydrates. (*See, e.g.*, No. 104: “Humans are mammals.”).



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to respond to them. They are properly considered a discovery device, subject to the limitations imposed upon other discovery devices, including the fact discovery cutoff date. AstraZeneca conceded its RFAs were used for discovery, and the authorities on which it relies authorizing late service are inapplicable. Nor are its RFAs directed toward the narrow issue of claim construction as represented to the court. For the foregoing reasons, Hanmi respectfully requests that AstraZeneca's request be denied.

Respectfully,

s/Mayra V. Tarantino

Mayra V. Tarantino

MVT:emp

cc: All Counsel of Record (via ECF & email)

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SYNTHES (U.S.A.), et al.,	:	CIVIL ACTION
Plaintiffs	:	
	:	
v.	:	NO. 04-1235
	:	
GLOBUS MEDICAL, INC., et al.,	:	
Defendants	:	

M E M O R A N D U M

STENGEL, J.

November 29, 2006

The defendants in this case have moved for a protective Order relieving them of all obligation to respond to the plaintiffs' third and fourth sets of requests for admissions, claiming that the sheer number of requests,¹ their repetitiveness, and remote relevance is grossly oppressive and abusive. For the following reasons, I will deny the motion in its entirety.

Under the Federal Rules of Civil Procedure, a party may serve upon any other party a written request for the admission, for purposes of the pending action only, of the truth of any matters within the scope of Rule 26(b)(1) set forth in the request that relate to statements or opinions of fact or of the application of law to fact, including the genuineness of any documents described in the request. See FED.R.CIV.P. 36(a). Any matter admitted under this rule is conclusively established unless the court on motion permits withdrawal or amendment of the admission. See FED.R.CIV.P. 36(b). An admission of fact made under Rule 36 is an

¹ The plaintiffs' first set of requests for admissions consisted of 126 requests; its second set consisted of 64 requests. The plaintiffs' first set of requests for admissions to defendant Binder had 64 requests. Defendant Globus substantively answered all of these requests. On September 25, 2006, the plaintiffs served a third set of 250 requests. On September 29, 2006, they served a fourth set of 118 requests, bringing the total number of requests for admissions to 622, a number far lower than the number of requests found excessive in the cases cited by the defendants.

“unassailable statement of fact that narrows the triable issues in the case.” Airco Industrial Gases, Inc. v. Teamsters Health & Welfare Pension Fund, 850 F.2d 1028, 1037 (3d Cir. 1988).

Requests for admission typically come late in discovery, or even after discovery has been completed and trial is imminent. Langer v. Monarch Life Ins. Co., 966 F.2d 786, 803 (3d Cir. 1992). If at that point a party is served with a request for admission of a fact that it now knows to be true, it must admit that fact, even if that admission will “gut its case and subject it to summary judgment.” Id. Rule 36 was intended to narrow the issues for trial, or altogether obviate the need for trial. Id.

After a careful review of both sets of requests for admissions, I find that the requests, which span 48 pages, are simple and straightforward recitations of fact which can be readily admitted or denied, that they relate to the authenticity, possession, or use of 23 documents, and that they concern seven topics with which the defendants should be quite familiar. The slight burden or expense of responding to these requests at this late stage in the discovery process is far outweighed by the benefit of facilitating proof with respect to the issues in the case, and of narrowing its triable issues.

An appropriate Order follows.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SYNTHES (U.S.A.) and	:	CIVIL ACTION
SYNTHES SPINE COMPANY, L.P.	:	
Plaintiffs	:	
	:	
v.	:	NO. 04-1235
	:	
GLOBUS MEDICAL, INC., et al.	:	
Defendants	:	

ORDER

STENGEL, J.

AND NOW, this 29th day of November, 2006, upon consideration of defendants' motion for a protective Order regarding the plaintiffs' third and fourth sets of requests for admissions (Document #161), the plaintiffs' response thereto (Document #164), and after a hearing on the motion with all parties present, it is hereby ORDERED that the motion is DENIED in its entirety.

IT IS FURTHER ORDERED that the defendants shall respond to both sets of requests for admissions within ten (10) days of the date of this Order.

BY THE COURT:

/s/ Lawrence F. Stengel
LAWRENCE F. STENGEL, J.